GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2263
ANSWERED ON:11.12.2015
Drug Regulations
Agrawal Shri Rajendra;Gogoi Shri Gaurav;Scindia Shri Jyotiraditya Madhavrao

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has taken note of ban on import of certain Indian drugs and warnings issued to a number of Indian drug manufacturers by American/ European drug regulators and the World Health Organisation (WHO) in the recent past;

(b) if so, the details thereof and the extent to which Indian drug industry and export are affected as a result thereof during the last three years and the current year;

(c) whether the Government has identified certain flaws in the drug regulation regime ranging from inadequate testing facilities and a lack of database to insufficient training to regulatory officials, and if so, the details thereof; and

(d) the steps taken/proposed to be taken by the Government to strengthen the drug regulation regime and raise the standards of pharmaceutical products as per global and
WHO standards; and

(e) the other measures taken/proposed to be taken by the Government to raise the credibility of Indian drugs and drug manufacturers in the global market?

Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a) & (b): In case of export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country. Isolated reports of the drugs not meeting the prescribed standards have appeared in the media and on the websites of the regulatory authorities of foreign countries, etc. from time to time. As per the recent media reports, regulatory action has been taken by USFDA against nine Indian Pharmaceutical Companies. Such instances impact our exports only marginally.

(c) & (d): The gaps and weaknesses of our regulatory structures have been identified and the Government has, with a view to strengthen the regulatory regime, approved a proposal to strengthen the drug regulatory structures both at the Centre and in the States at a total cost of Rs.1750/- crore. The strengthening will include construction of new offices and laboratories, re-

equipping existing laboratories, additional manpower, training, e-governance modules and IT infrastructure.

(e): With a view to raise the credibility of our drugs, the Department of Commerce has introduced bar coding on secondary and tertiary packs for exports for tracking and tracing the medicines. Once fully implemented, it will remove the chances of someone else selling medical products that are not genuine.